

**REMARKS**

Reconsideration and allowance of the present application are respectfully requested. Claims 1-9 and 12-20 are pending in this application. Claim 1 is an independent claim. Claims 10-11 are cancelled without any disclaimer of the subject matter contained therein. No new matter has been added.

**Premature Final Rejection**

Under M.P.E.P. § 706.07(a), a final rejection is premature "where the examiner introduces a new ground of rejection that is neither necessitated by applicant's amendment of the claims, nor based on information submitted in an information disclosure statement filed."

On August 24, 2010, Applicants filed a response to the final Office Action dated June 24, 2010. The response did not include any amendments to the claims. On December 20, 2010, the Office issued a communication stating that the final Office Action was withdrawn. Moreover, the Examiner issued an Interview Summary on December 27, 2010. The Interview Summary stated "that the finality of the previous Office [A]ction would be withdrawn."

Since the Examiner has made new grounds of rejections in reply to a response with no amendments, the outstanding Office Action should be made "non-final." Consequently, the finality of the outstanding Office Action is improper.

**Rejection under 35 U.S.C. § 101**

Claims 10-11 stand rejected under 35 U.S.C. § 101 as being directed to non-statutory subject matter. Claims 10-11 are cancelled without any disclaimer of the

subject matter contained therein, thereby rendering the rejection of claims 10-11 moot.

**Rejection under 35 U.S.C. § 103**

Claims 1-7 and 10-20 stand rejected under 35 U.S.C. § 103(a) as being anticipated Sabol et al. (US 2004/0122719) "Sabol," in view of Urquhart et al. (US 2004/0073454) "Urquhart." This rejection is respectfully traversed.

On page 3 of the Office Action, the Office Action states that claims 1-7 and 10-20 stand rejected under 35 U.S.C. § 102(e). However, this rejection is under the heading "Rejections under 35 U.S.C. § 103." Additionally, the Examiner's reasoning is based on a combination of two references, thereby indicating an obviousness rejection under 35 U.S.C. § 103. Consequently, the above evidence indicates that the "35 U.S.C. § 102(e)," was a typographical error and should have been "35 U.S.C. § 103(a)."

Claim 1 recites, *inter alia*, "storing, by a test system, test criteria for the data, correlated with the performance specification." At least this feature is not disclosed or suggested by Sabol and Urquhart, alone or in combination.

Sabol discloses a medical resource processing system. The system may provide material to a patient such as "structured video and/or audio recordings of questions and answers." Paragraph [0332] of Sabol. The material provided is for the patient. Resources that can be processed include reference sources which represent information about "medical events, medical conditions, disease state," and financial information. As recited in paragraph [0052] of Sabol,

The data resources do not, in general, require information to be gathered directly from the patient. Rather, these resources are more general in nature and may be obtained through data reference libraries, subscriptions, and so forth.

Thus, the data of Sabol represent general medical knowledge rather than a set of rules and performance specifications.

To maintain the validity and quality of such data, the validation and data management module 324 may carry out specific functions, typically bi-directionally, as indicated in FIG. 22. Such functions may include those of the reconciliation modules as indicated at reference numeral 326, which can reconcile or validate certain data, such as based upon time of entry, source of the data, or any other validating criteria. Where such reconciliation or validation is not available, such as due to conflicting updates or inputs, such matters may be flagged to a user for reconciliation.

Paragraph [0352] of Sabol.

On page 3 of the Office Action, the Examiner relies on paragraphs [0004], [0008] and [0332] of Sabol to teach the “storing,” of claim 1. However, paragraphs [0004], [0008] and [0332] of Sabol do not disclose or suggest “test criteria ... correlated with the performance specification.” For example, paragraph [0332] of Sabol discloses “structured video and/or audio recordings of questions and answers,” not any criteria for implementing a test. Moreover, paragraph [0004] of Sabol recognizes various data acquisition techniques, but fails to recite storing “test criteria ... correlated with the performance specification.”

Consequently, Sabol fails to disclose or suggest the “storing, by a test system, test criteria for the data, correlated with the performance specification,” as set forth in claim 1.

Urquhart discloses monitoring patient compliance with a prescribed drug regime. Monitoring devices are attached to drug dispensers and data about time and amount of drugs taken from the dispenser by a patient are collected. The data are subsequently transmitted to a server, where they are stored for analysis and later accessed by a physician. *See, e.g.,* paragraph [0014] of Urquhart.

However, neither Sabol nor Urquhart teach that the test criteria (i.e., the comparison between the recorded and prescribed dosage) are stored in a test system.

According to Urquhart, said criteria are rather an intrinsic property of a processing device used for data analysis. For example, paragraph [0040] of Urquhart provides:

PC 16 operates as a communication link to one or more remote stations. One such remote station is a PC 18 provided at a physician location. Another such remote station is a server 20, such as a webserver hosting the portal website designed to provide the analysis services discussed above. In particular, server 20 operates as a processing device which analyzes the received dosing history data and any information provided to the system by the physician and thereby generates analysis data used for a patient, including dosage histories, analysis of expected results of dosage history, treatment advice, and recommendations.

Consequently, one of ordinary skill in the art would hard-code the analysis criteria. As such, the analysis criteria are not stored by a test system. Therefore, Urquhart fails to disclose or suggest the “storing, by a test system, test criteria for the data, correlated with the performance specification,” as set forth in claim 1.

Since both Sabol and Urquhart fail to disclose or suggest the “storing,” of claim 1, Sabol and Urquhart, alone or in combination fail to render claim 1 obvious.

In the Examiner’s response to Applicants’ arguments on page 10 of the Office Action, the Examiner states that paragraph [0019] of Applicants’ Summary provides that a degree of compliance may lead to a simple Yes/No decision. (emphasis added). In other words, a Yes/No decision may be made after determining a degree of compliance. The degree of compliance cannot be interpreted as a simple Yes/No decision, as the Examiner has characterized the “degree of compliance.”

The Examiner points to paragraph [0289] of Sabol to support his contention that Sabol teaches the “degree of compliance.” Relevant portions of paragraph [0289] are provided below for the Examiner’s convenience.

The logic engine essentially contains the rules that coordinate the various functions carried out by the system. Such coordination includes accessing and storing data in the knowledge base, as well as execution of various computer-assisted data operating algorithms, such as for feature detection, diagnosis, acquisition, processing and decision-support. The logic engine can be rule-based, and may include a supervised learning or unsupervised learning system.

Nowhere in the above-recited paragraph does Sabol disclose a degree of compliance. The decision-support of Sabol does not disclose or suggest being a degree of compliance. The decision support can be any one of numerous factors which is not a "degree of compliance."

Moreover, the Examiner bases his opinion on the disclosure of a logic engine with the function of delivering "decision support." The description of said logic engine in paragraph [0289] of Sabol, however, is applicable to any general computing device. How the general functions are to be used in particular is gleaned from the context of Sabol. Usage of said decision support functionality to determine a degree of compliance between data and performance specification is not disclosed in Sabol. From the general context of Sabol, "decision support" is the presentation of data to a patient and/or physician, in order to aid them in making decisions. *See*, paragraph [0332] of Sabol.

Claims 8-9 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Sabol in view of Urquhart and further in view of Miller et al. (US 5,446,653) "Miller." This rejection is respectfully traversed.

The Examiner correctly acknowledges that the features of claims 8-9 are not disclosed or suggested by Sabo and Urquhart. However, the Examiner alleges that these features are taught by Miller. Even if Miller taught the features of claims 8-9 (which Applicants do not admit) and that Miller could be properly combined with Sabol and Urquhart (which Applicants do not admit), Miller fails to cure the deficiencies of Sabol and Urquhart as described above with reference to claim 1. Therefore, Sabol, Urquhart and Miller fail to render claims 8-9 obvious.

For at least the foregoing reasons, Applicants respectfully request that the Examiner withdraw the rejections under 35 U.S.C. § 103.

**CONCLUSION**

Accordingly, in view of the above remarks, reconsideration of the objections and rejections and allowance of each of claims 1-9 and 12-20 in connection with the present application is earnestly solicited.

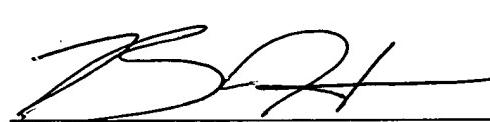
Should there be any outstanding matters that need to be resolved in the present application, the Examiner is respectfully requested to contact Donald J. Daley at the telephone number of the undersigned below.

If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies, to charge payment or credit any overpayment to Deposit Account No. 08-0750 for any additional fees required under 37 C.F.R. § 1.16 or under 37 C.F.R. § 1.17; particularly, extension of time fees.

Respectfully submitted,

HARNESS, DICKEY, & PIERCE, P.L.C.

By



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